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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0208]

Interim Melamine and Melamine Analogues Safety/Risk Assessment; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled, "Interim Melamine and Melamine Analogues Safety/Risk Assessment." The interim safety/risk assessment describes the risk to human health associated with eating pork, chicken, fish, and eggs from animals that were inadvertently fed animal feed that contained melamine and its analogues (cyanuric acid, ammelide and ammeline). FDA is seeking public comment on the interim safety/risk assessment to assist the agency and the Food Safety and Inspection Service (FSIS) at the U. S. Department of Agriculture (USDA) in the ongoing investigation of contaminated vegetable protein products imported from China that were mislabeled as "wheat gluten" and "rice protein concentrate," and ensuring the safety of the U.S. food supply.

DATES: Comments on the interim safety/risk assessment must be submitted by [*insert date 30 days after date of publication of the* **Federal Register**].

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

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Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: P. Michael Bolger, Chief, Risk Assessment Staff, Center for Food Safety and Applied Nutrition (HFS–308), 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1941, FAX 301–436–2632, or e-mail: *Mike.Bolger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The interim safety/risk assessment was prepared by FDA in collaboration with FSIS and in consultation with the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Homeland Security. The purpose of the safety/risk assessment is to assist FDA and FSIS in the ongoing investigation of contaminated vegetable protein products imported from China that were mislabeled as "wheat gluten" and "rice protein concentrate," and ensuring the safety of the U.S. food supply. The interim safety/risk assessment concludes that, based on currently available data and information, the consumption of even large amounts of pork, chicken, fish, and/or eggs from animals that had been inadvertently fed animal feed contaminated with melamine and its analogues is very unlikely to pose a human health risk. This safety/risk assessment was developed rapidly due to the extremely time-sensitive need to understand the nature of the potential risk. However, we are seeking public comment on this interim safety/risk assessment, and in addition it will undergo expert peer review.

II. Safety/Risk Assessment

A human health safety/risk assessment is a scientifically-based methodology used to estimate risk to human health from exposure to specific

compounds such as contaminant(s) in food. The interim melamine and its analogues safety/risk assessment addresses:

(1) The chemical characteristics of melamine and its analogues;

(2) The toxicological profile of melamine and its analogues, including the observed results from controlled animal studies conducted with melamine; and

(3) The likelihood that consumption of pork, chicken, fish and eggs from animals fed feed contaminated with melamine and its analogues poses a health risk to humans.

FDA used the following methodology to develop the safety/risk assessment. The safety/risk assessment was based on the currently available scientific data and information. FDA estimated human exposure to melamine and its analogues based on the estimated levels in specific foods and the estimated consumption of those foods. The agency compared the exposure estimate to a "Tolerable Daily Intake" level, which was derived using available toxicity data on the level of melamine that did not cause adverse renal effects in a laboratory-animal (13-week rat) bioassay study. FDA adjusted this level, "the No Observed Adverse Effect Level" for uncertainty in the data by dividing by a safety/uncertainty factor of 100 to account for differences in sensitivity within and across species.

Recognizing the time-sensitive need for the safety/risk assessment, FDA invites comments concerning:

(1) The assessment approach used;

(2) The assumptions made;

(3) The data used; and

(4) The transparency and clarity of the report.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

The interim safety/risk assessment is available electronically at *http://www.cfsan.fda.gov/~dms/melamra.html.*

Dated: May 22, 2007.

May 22, 2007.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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